510(k) SUMMARY

SUBMITTED BY

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(949) 453-3200

February 22, 2001

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Vertebral Body Replacement
Common/Usual Name: Vertebral Body Replacement
Product Classification: Class II
Proprietary Name: GEO™ Structure

PREDICATE DEVICE

The predicate device is the Stackable Cage™ System that is currently manufactured and distributed by DePuy AcroMed™, Inc.

INDICATIONS-FOR-USE

The GEO Structure is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The GEO structure is also indicated for treating fractures of the thoracic and lumbar spine. The GEO Structure is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

DEVICE DESCRIPTION

The GEO Structure is an oval shaped, vertebral body replacement device manufactured from surgical implant grade titanium alloy as described by ASTM F-1108 (Ti 6Al 4V). The implant has a satin finish surface and is available in various sizes. The GEO Structure is provided either sterile or nonsterile.

COMPARISON TO THE PREDICATE DEVICE

The GEO Structure is substantially equivalent to the Stackable Cage System that is currently manufactured and distributed by DePuy AcroMed, Inc. Both implants are used

to treat the same conditions, have essentially the same precautions and contraindications for use, and have equivalent potential for complications for the risk of use. In addition, they both represent a basic design concept in terms of safety and effectiveness, and differ only in minor details. Based on the basic design concept, the use of established well known materials, feature comparisons, mechanical testing, indications for use, preproduction quality assurance planning and engineering analysis, INTERPORE CROSS International believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to the existing legally marketed device.

DISCUSSION OF NONCLINICAL TESTS

Data regarding the functional performance of the proposed GEO Structure has been generated. Biomechanical testing, including static axial compression, torsional loading, shear compression and expulsion testing indicates that the proposed GEO Structure meets or exceeds all functional requirements and supports its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Ms. Lynn M. Rodarti
Manager, Regulatory and Clinical Affairs
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181 Technology Drive
Irvine, California 92618

Re: K010530
Device Name: GEO Structure
Regulation Number: unclassified
Product Code: MQP
Dated: June 18, 2001
Received: June 19, 2001

Dear Ms. Rodarti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010530

Device Name: **GEO Structure**

Indications-For-Use:

The GEO Structure is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The GEO structure is also indicated for treating fractures of the thoracic and lumbar spine. The GEO Structure is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010530

Prescription Use ✓ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

(Optional Format 1-2-96)